

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES	)
INTERNATIONAL SRL,	)
a corporation of Barbados,	)
	)
Plaintiff,	)
	) C. A. No. 06-620 (KAJ)
v.	)
	)
ANDRX PHARMACEUTICALS, LLC and	)
ANDRX CORPORATION,	)
	)
Defendants.	)

**ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants, Andrx Pharmaceuticals, LLC and Andrx Corporation (hereinafter "Andrx"), by its attorneys, answer the Complaint herein as follows:

1. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 1 of the Complaint.
2. Andrx admits the allegations contained in paragraph 2 of the Complaint.
3. Andrx admits the allegations contained in paragraph 3 of the Complaint.
4. Andrx admits the allegations contained in paragraph 4 of the Complaint.
5. Andrx admits the allegations contained in paragraph 5 of the Complaint.
6. Andrx admits that this action arises under the patent laws of the United States of America and specifically under 35 U.S.C. §271(e) and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Andrx denies the remaining allegations contained in paragraph 6 of the Complaint.
7. Andrx admits the allegations contained in paragraph 7 of the Complaint.

8. Andrx admits that it manufactures pharmaceutical products that are sold and used, including through subsidiaries, throughout the United States, including this District. Andrx denies that it manufactures bulk pharmaceuticals.

9. Andrx repeats the admissions and denials of paragraphs 1-8 above in response to the allegations in paragraph 9 of the Complaint.

10. To the extent that Paragraph 10 of the Complaint states conclusions of law, Andrx states that no response is required. To the extent that Paragraph 10 of the Complaint states allegations of fact, Andrx admits that United States Patent No. 7,108,866 ("the '886 patent") was issued on September 19, 2006 to Biovail, which is listed on the patent as the assignee of the named inventors, Kenneth Stephen Albert and Paul Jose Maes.

11. Andrx admits the allegations contained in paragraph 11 of the Complaint.

12. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 12 of the Complaint.

13. Andrx admits the allegations contained in paragraph 13 of the Complaint.

14. Andrx admits the allegations contained in paragraph 14 of the Complaint, except is without information sufficient to form a belief as to the allegation as to when Biovail received the notice letter.

15. Andrx denies the allegations in paragraph 15 of the Complaint.

16. Andrx denies the allegations in paragraph 16 of the Complaint.

17. Andrx denies the allegations in paragraph 17 of the Complaint.

18. Andrx denies the allegations in paragraph 18 of the Complaint.

**FIRST DEFENSE**

19. Upon information and belief, Andrx has not infringed any valid and enforceable claim of the '866 patent.

**SECOND DEFENSE**

20. Upon information and belief, Andrx alleges that the '866 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §102.

**THIRD DEFENSE**

21. Upon information and belief, Andrx alleges that the '866 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §103.

**FOURTH DEFENSE**

22. Upon information and belief, Andrx alleges that the '866 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §112.

**COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

Andrx counterclaims against Plaintiff, Biovail Laboratories International SRL, for declaratory relief and alleges:

23. Subject matter jurisdiction for this counterclaim for declaratory judgment is based upon 28 U.S.C. §§ 1338, 2201, and 2202 and Rule 13 of the Federal Rules of Civil Procedure. An actual case or controversy exists between Biovail and Andrx based upon Biovail having filed this complaint against Andrx.

**COUNT I**

24. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19- 23 of this Answer.

25. Andrx is entitled to a judgment declaring that it has not infringed any valid and enforceable claim of the '866 patent.

**COUNT II**

26. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-23 of this Answer.

27. Andrx is entitled to a judgment declaring that the '866 patent is invalid for failure to comply with one or more of the requirements for patentability in 35 U.S.C. §102.

**COUNT III**

28. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-23 of this Answer.

29. Andrx is entitled to a judgment declaring that the '866 patent is invalid for failure to comply with one or more of the requirements for patentability in 35 U.S.C. §103.

**COUNT IV**

30. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-23 of this Answer.

31. Andrx is entitled to a judgment declaring that the '866 patent is invalid for failure to comply with one or more of the requirements for patentability in 35 U.S.C. §112.

**COUNT V**

32. Andrx incorporates by reference and re-alleges the allegations in paragraphs 19-23 of this Answer.

33. Biovail's allegations of infringement are wholly unjustified, and, on information and belief, were asserted for the improper purpose of delaying the entry of Andrx's proposed generic product, which will compete with Biovail's diltiazem product. The case should be deemed "exceptional" under 35 U.S.C. § 285. Andrx is entitled to the relief provided by 35 U.S.C. § 285, including attorney fees as a result of Biovail's actions.

**WHEREFORE**, Andrx demands:

- A. That the Complaint filed herein be dismissed and that the Plaintiff have and recover nothing by reason thereof;
- B. that United States Patent No. 7,108,866 be declared and adjudged invalid;
- C. that United States Patent No. 7,108,866 be declared and adjudged unenforceable;
- D. that it be declared and adjudged that Andrx has not infringed and will not infringe any valid and enforceable claim of United States Patent No. 7,108,866;
- E. that this case be adjudged and decreed an exceptional case under 35 U.S.C. § 285 and that Andrx be entitled to recover reasonable attorneys' fees and costs incurred in this action;

F. that Andrx be awarded damages, including punitive damages, for the assertion of a patent which Counterclaim Defendant knew to be invalid and/or unenforceable;

G. such other and further relief as the Court deems just and equitable.

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*Attorneys for Defendants  
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Andrx Corporation*

Dated: October 12, 2006

755486 / 30015

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

**CERTIFICATE OF SERVICE**

I, Richard L. Horwitz, hereby certify that on October 12, 2006, the attached document was hand-delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

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I hereby certify that on October 12, 2006, I have Electronically Mailed the documents to the following non-registered participants:

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